



THE 1st ASEAN MEDICAL DEVICE COMMITTEE (AMDC) MEETING AND RELATED EVENTS

30th NOV - 3rd DEC 2015
KUALA LUMPUR, MALAYSIA



INTRODUCTION TO ASEAN MEDICAL DEVICE DIRECTIVE (AMMD)

**T.SASIKALA
MEDICAL DEVICE AUTHORITY
MINISTRY OF HEALTH MALAYSIA**

Southeast Asia Map



**Member
economies:**

**Malaysia,
Philippines,
Thailand,
Indonesia,
Singapore,
Vietnam,
Brunei
Darussalam
Lao PDR,
Cambodia,
Singapore**

CONTENT

- **BACKGROUND**
- **AMDD**
- **COMPARISON BETWEEN AMDD & ACT 737**
- **CHRONOLOGY**
- **SUMMARY**

BACKGROUND

- **ASEAN Consultative Committee for Standards and Quality (ACCSQ)**
ACCSQ was formed by the ASEAN Economic Minister in 1992

Aim of ACCSQ is to **remove technical barriers to trades** in order to facilitate and realize the ASEAN Free Trade Area (AFTA).

Focus:

- harmonisation of standards- technical requirements
- development of MRA on conformity assessment
- development of harmonised regulatory regime

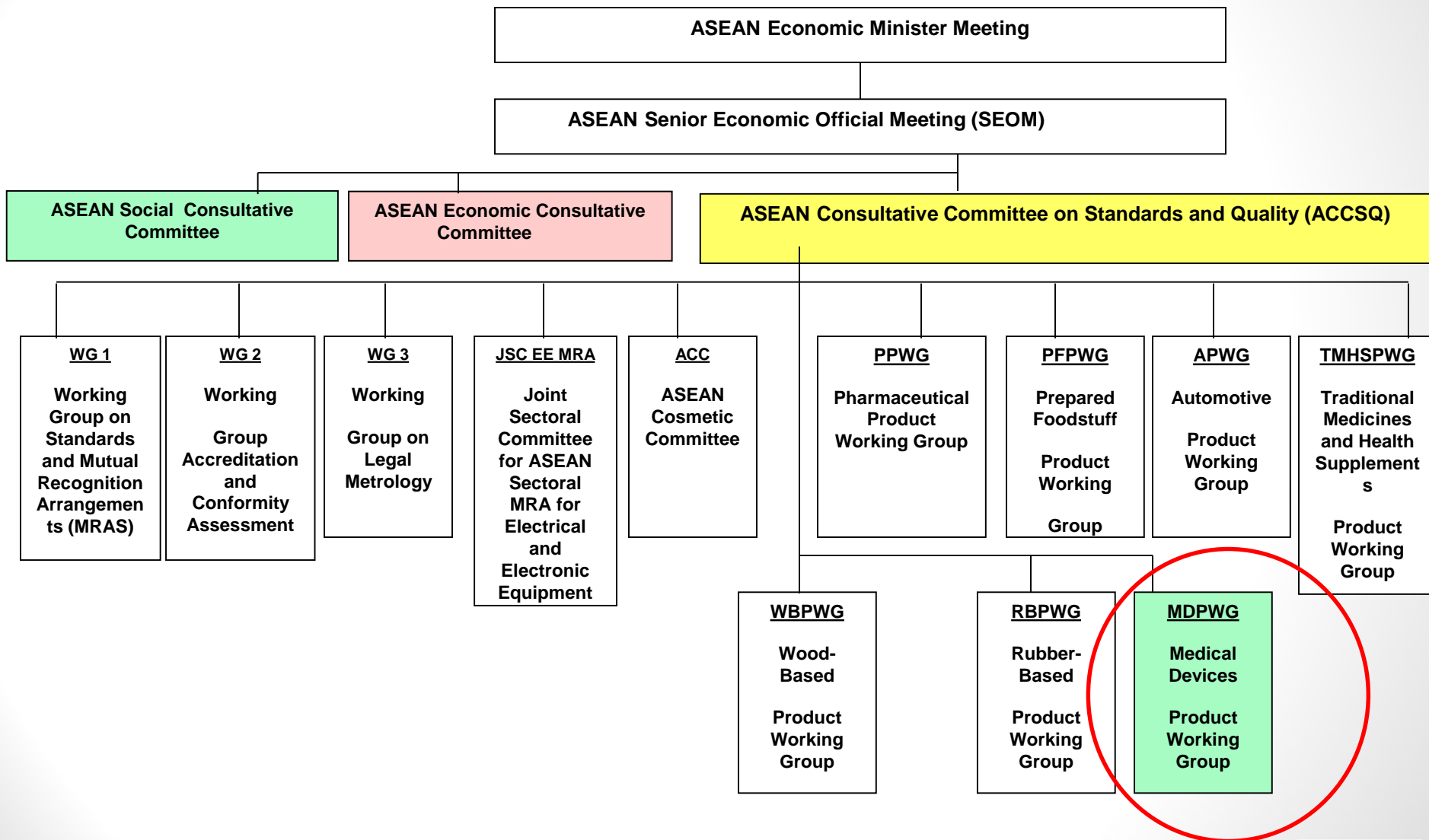
- **Product Working Group on Medical Device (ACCSQ-MDPWG)**
ACCSQ-MDPWG was established to fast-track integration of the twelve priority sectors including healthcare sector , 2005.

- **Objectives:**

ACCSQ-MDPWG to implement measures to **facilitate the integration of medical device within ASEAN Member Economies.**



ACCSQ Structure



Medical device Regulation toward the AEC 2015

Goal of creating an ASEAN Economic Community by 2015,
with fast-track integration of the 12 priority sectors



- | | | |
|----------------------|------------------------|--|
| 1. Agro-base product | 5. Electrical | 9. Health care product (drug, traditional drug, cosmetic and Medical Devices) |
| 2. Air Travel | 6. Rubber base product | 10. Textiles and apparels |
| 3. Automotive | 7. Tourism | 11. Wood-based product |
| 4. e-ASEAN | 8. Fisheries | 12. Logistics Services |

BACKGROUND OF AMDD

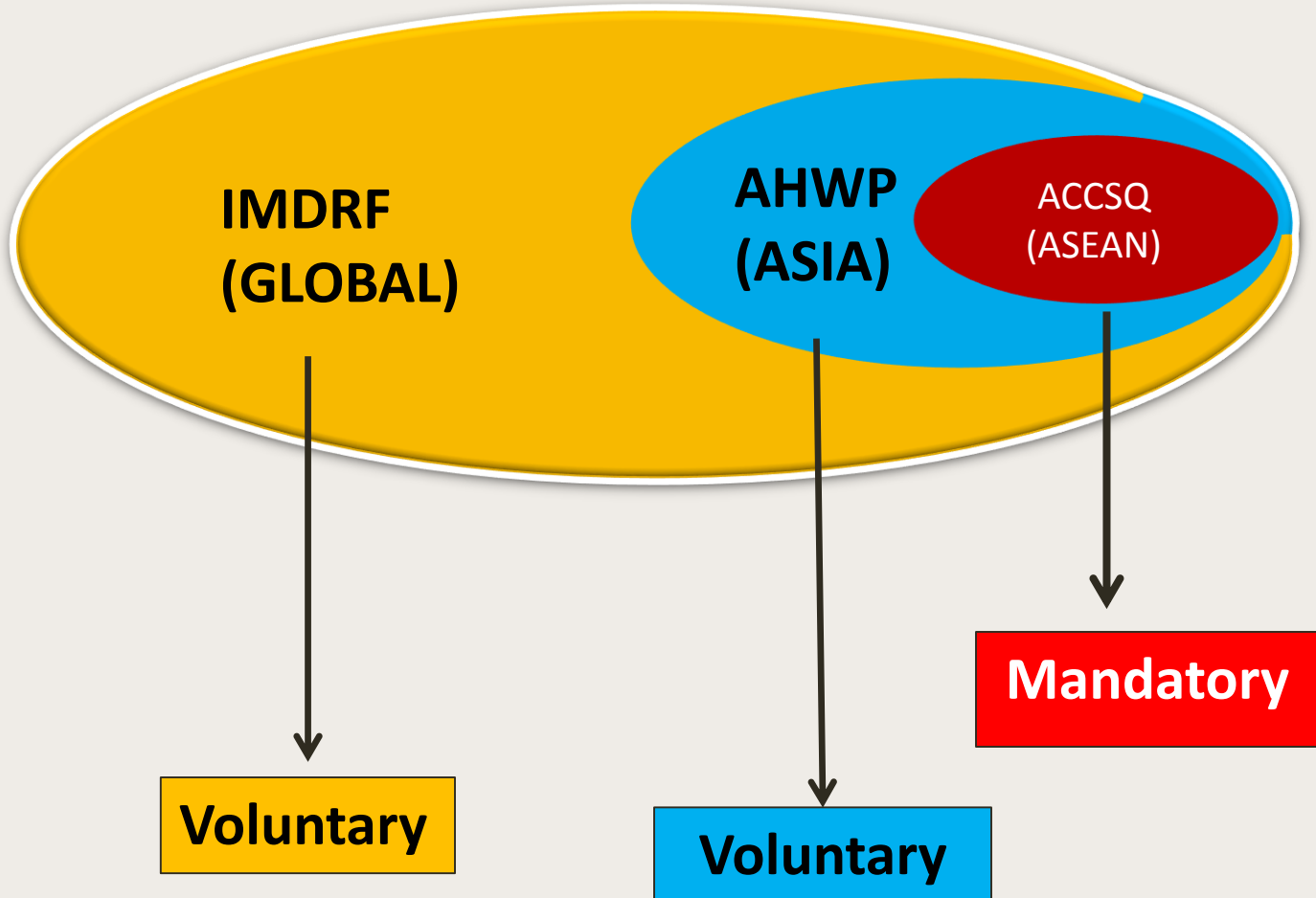
- **AEC Blueprint, Action Item - Para 19 (i):**
 - Harmonise standards, technical regulations and conformity assessment procedures through their alignment with international practices, where applicable
- **Harmonization of medical device regulation:-**
 - Reduce the time to market access & facilitate trade
 - Reduce the cost to market
 - Improve regulatory efficiency
 - Enhancement of public health protection

AMDD CHRONOLOGY

- AMDD becomes effective when ASEAN Member States deposit instruments of ratification with ASEAN Secretariat General

HARMONIZATION OF MEDICAL DEVICES REGULATION

GROUP OF HARMONIZATION



WHAT IS AMDD?

The AMDD is a legal and institutional framework for the ASEAN Community to harmonise medical devices regulation in the region. It is a common medical device directive in ASEAN among Member States

A key objective of the AMDD is to ensure only safe, effective and quality medical devices are placed in the ASEAN region.

Harmonization in AMDD:

- Definition of medical device
- Risk based classification
- Standards -a similar level of quality assurance (major features)
- CSDT
- EPSP
- PMAS
- Registration of product
- Licencing of establishment
- QMS ISO13485/ISO14971

HARMONIZATION OF MEDICAL DEVICE REGULATION

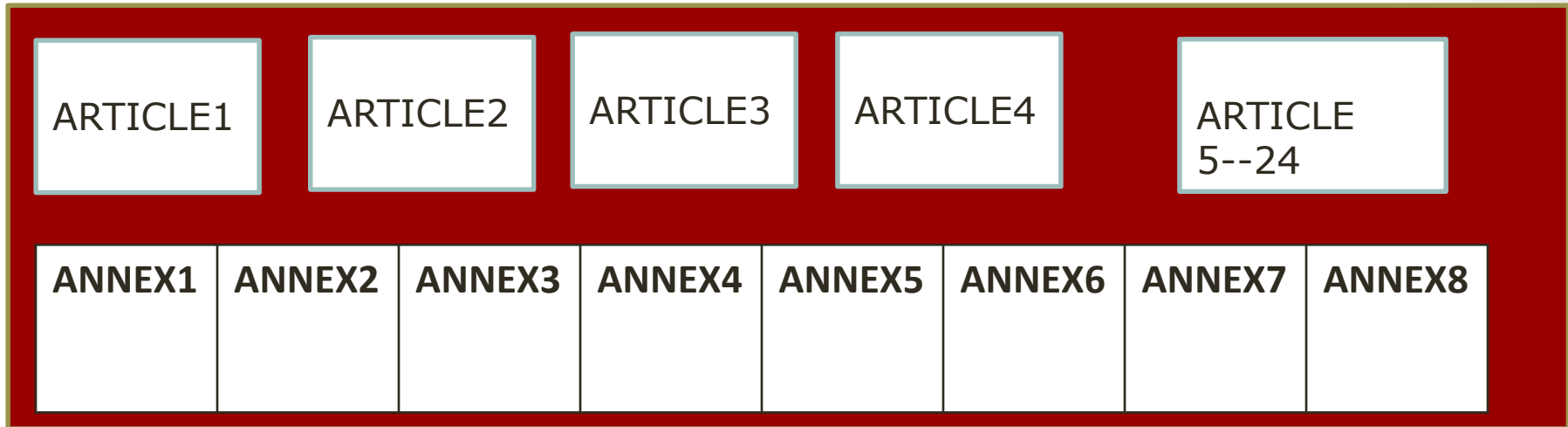
- Reduce the time to place in the market & facilitate trade
- Reduce the cost to place in the market
- Improve regulatory efficiency
- Ensure safe and effective medical device place in the market
- Enhancement of public health protection



INTRODUCTION TO ASEAN MEDICAL DEVICE DIRECTIVE (AMMD)

ASEAN HARMONISED REGULATORY REQUIREMENT....
INTRODUCTION TO AMDD

AMDD STRUCTURE



Transpose AMDD into National Laws

National Laws of Member States for Medical Device Control

**MALAYSIA has transposed almost all AMDD articles in
Act 737**

AMDD STRUCTURE

ASEAN MEDICAL DEVICE DIRECTIVE

ARTICLE	PROVISION
ARTICLE 1	GENERAL PROVISION
ARTICLE 2	DEFINITION AND SCOPE
ARTICLE 3	ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICE
ARTICLE 4	CLASSIFICATION OF MEDICAL DEVICES
ARTICLE 5	CONFORMITY ASSESSMENT OF MEDICAL DEVICE
ARTICLE 6	REGISTRATION AND PLACEMENT ON THE MARKET
ARTICLE 7	LICENSING OF PERSON RESPONSIBLE FOR PLACING MEDICAL DEVICES ON THE MARKETS OF MEMBER STATES
ARTICLE 8	TECHNICAL DOCUMENTS FOR MEDICAL DEVICES
ARTICLE 9	REFERENCE TO TECHNICAL STANDARDS
ARTICLE 10	LABELLING
ARTICLE 11	MEDICAL DEVICES CLAIMS
ARTICLE 12	POST-MARKETING ALERT SYSTEM
ARTICLE 13	CLINICAL INVESTIGATION

AMDD ARTICLES	AMDD PROVISION
ARTICLE 14	INSTITUTIONAL ARRANGMENTS
ARTICLE 15	SAFEGUARD CLAUSES
ARTICLE 16	CONFIDENTIALITY
ARTICLE 17	SPECIAL CASES
ARTICLE 18	IMPLEMENTATION
ARTICLE 19	REVISIONS, MODIFICATIONS AND AMENDMENTS
ARTICLE 20	DISPUTE SETTLEMENT
ARTICLE 21	RESERVATIONS
ARTICLE 22	ENTRY INTO FORCE
ARTICLE 23	ANNEXES
ARTICLE 24	DEPOSITARY

AMDD ANNEXES

ANNEX	CONTENTS
ANNEX1	ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES
ANNEX 2	Risk Classification Rules for Medical Devices other than IVD Medical Devices
ANNEX 3	Risk Classification Rules for IVD Medical Devices
ANNEX 4	ASEAN Common Submission Dossier Template
ANNEX 5	Post Marketing Alert System (PMAS) Requirements
ANNEX 6	Components Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC)
ANNEX 7	Labelling Requirements
ANNEX 8	Clinical Investigation

AMDD STRUCTURE

ARTICLE	PROVISION	CONTENTS
ARTICLE1	GENERAL PROVISION	<p>Each Member State shall undertake all necessary measures to ensure that only medical devices which conform to the provisions of this ASEAN Agreement on Medical Device Directive and its Annexes may be placed on the markets of that Member State</p> <p>AMS (ASEAN Member State) shall require that the person responsible for placing the medical device in that Member State or the authorised representative shall register the medical device with the Regulatory Authority of that Member State.</p> <p>AMS shall require that the person responsible for placing the medical device in that Member State or the authorised representative shall be licensed by the Regulatory Authority of that Member State before placing the medical device in that Member State.</p>

ARTICLE	PROVISION	CONTENTS
ARTICLE 2	DEFINITION AND SCOPE	<p>This Agreement shall apply to medical devices and their accessories</p> <p>medical device</p> <p>“authorised representative” means any person in a Member State who, explicitly designated by the product owner, acts and may be addressed by authorities and bodies in a Member State instead of the product owner with regard to the latter’s obligations under this Agreement, and relevant laws and regulations of the Member State.</p> <p>“authorised distributor”, in relation to the placing on the market of a medical device, means any person who has been authorised by the product owner or authorised representative to distribute the medical device in that Member State.</p> <p>“manufacture”, in relation to a medical device, means to make, fabricate, produce or process the medical device and includes: any process carried out in the course of so making, fabricating, producing or processing the medical device; and/or the packaging and labelling of the medical device before it is supplied.</p>

ARTICLE	PROVISION	CONTENTS
ARTICLE 2	DEFINITION AND SCOPE	<p>“physical manufacturer”, in relation to a medical device, means any person who performs the activity of manufacture.</p> <p>“placing on the market” means the making available in return for payment or free of charge of a medical device other than a device intended for clinical investigation, with a view to distribution and/or use on the market of a Member State.</p> <p>“product owner”, in relation to a medical device, means any person who:</p> <ul style="list-style-type: none">supplies the medical device under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; andis responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the medical device, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

AMDD STRUCTURE

ARTICLE	PROVISION	CONTENTS
ARTICLE 3	ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICE	Medical devices shall meet the essential principles set out in Annex 1 ANNEX 1: ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES
ARTICLE 4	CLASSIFICATION OF MEDICAL DEVICES	Medical devices shall be classified into the following four classes, in accordance with risk classification rules set out in Annex 2 (Risk Classification Rules for Medical Devices other than IVD Devices) and Annex 3 (Risk Classification Rules for IVD Devices): Class Risk Level A Low risk B Low-moderate risk C Moderate-high risk D High risk ANNEX 2 ; RISK CLASSIFICATION RULES FORMEDICAL DEVICES OTHER THAN IVD MEDICAL DEVICES ANNEX 3; 3RISK CLASSIFICATION RULES FOR IVD MEDICAL DEVICES

AMDD STRUCTURE

ARTICLE	PROVISION	CONTENTS
ARTICLE 5	CONFORMITY ASSESSMENT OF MEDICAL DEVICE	A medical device, which is required to be assessed by a Member State and intended to be placed on the market of that Member State, shall be assessed by the Regulatory Authority of that Member State , or any appointed bodies recognised by that Member State, for conformity and compliance unless the medical device has been exempted
ARTICLE 6	REGISTRATION AND PLACEMENT ON THE MARKET	<p>A medical device which has been assessed by the Regulatory Authority of that Member State or any appointed bodies recognised by that Member State to be in conformity and in compliance with the requirements laid down in this Agreement may be placed on the market of that Member State.</p> <p>A medical device to be placed on the market of a Member State shall be registered with the Regulatory Authority of that Member State. The Regulatory Authority of the Member State may exempt certain medical devices from the requirement for registration where appropriate.</p>

AMDD STRUCTURE

ARTICLE	PROVISION	CONTENTS
ARTICLE 7	LICENSING OF PERSON RESPONSIBLE FOR PLACING MEDICAL DEVICES ON THE MARKETS OF MEMBER STATES	Each Member State shall require a person who is responsible for placing medical devices on the market to be licensed by the Regulatory Authority of that Member State before the medical devices are placed on the market of that Member State.
ARTICLE 8	TECHNICAL DOCUMENTS FOR MEDICAL DEVICES	Member States shall undertake appropriate measures to adopt and implement the following common technical documents: ANNEX 4 ASEAN COMMON SUBMISSION DOSSIER TEMPLATE ANNEX 5 ; POST MARKETING ALERT SYSTEM (PMAS) REQUIREMENTS ANNEX 6 : COMPONENTS ELEMENTS OF A PRODUCT OWNER'S OR PHYSICAL MANUFACTURER'S DECLARATION OF CONFORMITY (DOC)
ARTICLE 9	REFERENCE TO TECHNICAL STANDARDS	Technical standards recognised by the AMDC or other technical standards accepted by the Regulatory Authority of a Member State

AMDD STRUCTURE

ARTICLE	PROVISION	ANNEX
ARTICLE 10	LABELLING	<p>A medical device shall be labelled in accordance with the requirements of the Member State prior to placing on the market in that Member State. Member States may set the requirement for having the label of a medical device in their national languages.</p> <p>ANNEX 7: LABELLING REQUIREMENTS</p>
ARTICLE 11	MEDICAL DEVICES CLAIMS	<p>Medical device claims shall be subject to regulatory control of Member States. Claimed benefits of a medical device shall be justified by substantial evidence in accordance with the requirements as set out in Annex 1</p> <p>ANNEX 1: ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL</p>

ARTICLE	PROVISION	ANNEX
ARTICLE 12	POST-MARKETING ALERT SYSTEM	<p>Member States shall take the necessary steps to ensure that any information brought to their knowledge, in accordance with the provisions of this Agreement, regarding the incidents involving a medical device as mentioned below is recorded and evaluated when appropriate:</p> <ul style="list-style-type: none">a) any malfunction or deterioration in the characteristics or performance of a medical device,b) product recall <p>Member State shall inform the other Member States</p> <p>Each Member State shall require</p> <ul style="list-style-type: none">• keep all relevant records• inform the Regulatory Authority, any adverse• inform the Regulatory Authority, to perform FSCA.

ARTICLE	PROVISION	ANNEX
ARTICLE 13	CLINICAL INVESTIGATION	<p>Member States shall put in place an appropriate system for the conduct of clinical investigation of medical devices, taking into account the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and any subsequent amendments or revisions to this Declaration by the World Medical Association.</p> <p>The product owner, or his authorised representative, or the sponsor of the clinical investigation in a Member State, register with the Regulatory Authority of that Member State in which the investigations are to be conducted.</p> <p>Where a clinical investigation is refused or halted , inform all Member States and the AMDC.</p> <p>Where a Member State has called for a significant modification or temporary interruption of a clinical investigation, that Member State may inform all Member States and the AMDC concerned about its actions and the grounds for the actions taken.</p> <p>Notify of the end of the clinical investigation</p> <p>In the case of early termination of the clinical investigation on safety grounds, this notification may be communicated to the Regulatory Authority of all Member States where the clinical investigation is carried out.</p> <p>ANNEX 8:CLINICAL INVESTIGATION</p>

ARTICLE 14 – INSTITUTIONAL ARRANGEMENTS

- ASEAN Medical Device Committee (AMDC) is to be established for the coordination, review and monitoring of the implementation of AMDD.
- The ACCSQ and ASEAN Secretariat shall provide support in coordinating and monitoring the implementation of this Agreement and assist the AMDC in all matters relating thereto
- The AMDC may establish ASEAN Medical Device Technical Committee (AMDTC) to assist the AMDC in reviewing the technical and safety issues.



ARTICLE 15 – SAFEGUARD

- A medical device placed on the market of Member States shall not cause damage to human health when applied as indicated by the Product Owner.
- Where a RA ascertains that a medical device placed on the market of a Member State,
 - When correctly installed, maintained and used for their intended purpose may compromise the health or safety of patients, users or other persons,
 - It shall take all appropriate interim measures to withdraw such medical device from the market or prohibit or restrict their being placed on the market or put into service.
- That Member State shall immediately inform the other Member States of any such measures, indicating the reasons and if it is due to:-
 - failure to meet the essential requirements in Article 3;
 - incorrect application of its applied standards referred to in Article 9,
 - inadequacies in the standards applied to demonstrate conformity to the essential requirements.



ARTICLE 16 – CONFIDENTIALITY

- Without prejudice to the existing national laws and regulations, Member States are to ensure that all the parties involved in the application of the AMDD are **bound to observe confidentiality** with regard to all information obtained in carrying out their tasks, with exception cited in the Article.

ARTICLE 17 – SPECIAL CASES

- A Member State may **refuse to register** or provisionally prohibit the marketing of a medical device or subject it to special conditions if
 - the medical device which complies with the requirements of the AMDD represents a hazard to public health or for reasons specific to **religious or cultural sensitivity**.
 - A Member State who places a **restriction or temporary ban** on specific medical devices is required to notify the other Member States and the AMDC of such measures taken.

ARTICLE 18 – IMPLEMENTATION

- Member States are to undertake appropriate measures
 - To implement the AMDD in their jurisdiction.
 - To ensure that the technical infrastructures necessary are in place to implement the AMDD.
 - To ensure that the texts of such provisions of national laws, which they adopt in the area stated by the Directive are communicated to other Member States , ASEAN Secretariat, and the AMDC.
 - To ensure that post marketing surveillance is in place and shall have full authority to enforce the law on MDs found to be not complying with the AMDD.

ARTICLE 19 – REVISIONS, MODIFICATIONS & AMENDMENTS

- The provisions of the AMDD may be revised, modified or amended by written agreement of all Member States.
- Annexes may be revised, modified or amended subject to endorsement of AMDC.

ARTICLE 20 – DISPUTE SETTLEMENT

- The ASEAN Protocol on Enhanced Dispute Settlement Mechanism was signed on 29 November 2004 in Vientiane, Lao PDR.
- The Protocol and amendments thereto, will apply to any dispute arising from, or any difference between Member States concerning their interpretation or implementation, and or any application of any provisions under the AMDD.

ARTICLE 21 – RESERVATIONS

- Member States shall make no reservation with respect to any of the provisions of the AMDD.

ARTICLE 22 – ENTRY INTO FORCE

- The AMDD shall enter into force on **1 January 2015** and **shall be in force only** among the Member States that have **ratified and/or accepted it.**

ARTICLE 23 – ANNEXES

- Annexes to AMDD are an integral part of the agreement

ARTICLE 24 – DEPOSITORY

- The AMDD shall be deposited with Secretary-General of ASEAN

INTRODUCTION TO ASEAN MEDICAL DEVICE DIRECTIVE (AMMD)

COMPARISON BETWEEN AMDD & ACT 737

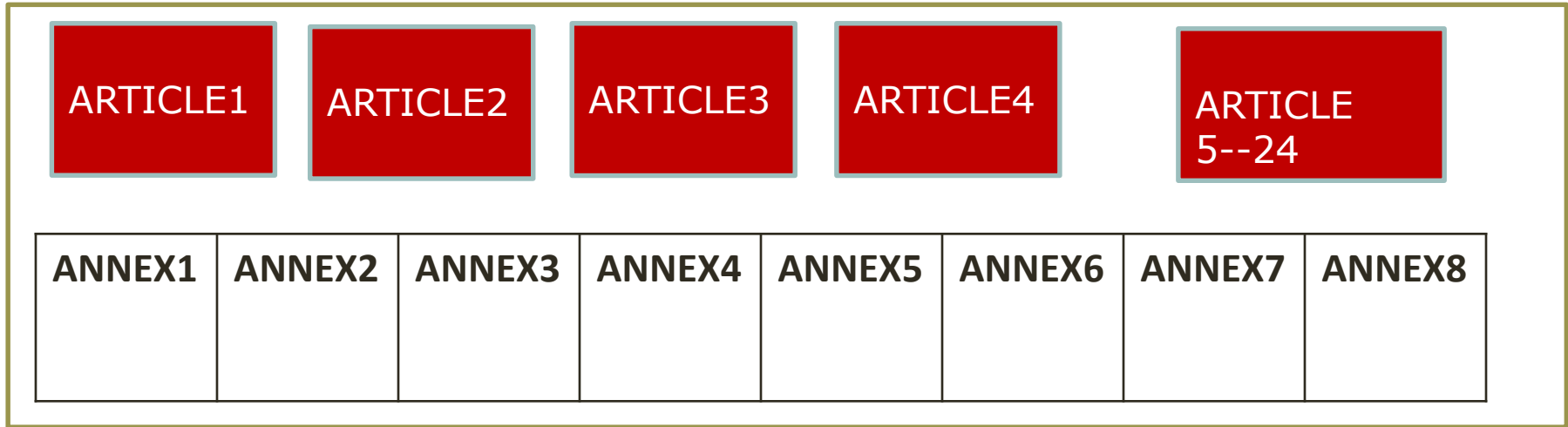
AMDD ARTICLES	AMDD PROVISION	(i)Malaysia Medical Device Act (“Act 737”) (ii)Medical Device Regulations 2012 (“Reg 2012”)
ARTICLE 1	Member States shall undertake all necessary measures to ensure that only medical devices which conform to the provisions of AMDD and its Annexes may be placed in the markets of Member States.	By conforming to Medical Device Authority vide Act 738, and bringing Act 738 into operation on 15 Mar 2012, Malaysia is proactive and taking steps to align to AMDD.
ARTICLE 2	Definition and Scope of Medical Device	The definition of a medical device, as defined in Act 737, is similar to AMDD.
ARTICLE 3	Essential Principles of Safety and Performance of Medical Device	Pursuant to section 4 of Act 737, a manufacturer shall ensure that a medical device conform to the Essential Principles of Safety and Performance (“EPSP”). This control is aligned to the AMDD.
ARTICLE 4	Classification of Medical Devices	Pursuant to section 3 of Act 737, an establishment intending to register a medical device with MDA must classify that medical device. This classification should be performed according to a set of risk based classification rules. The risk classification is divided into 4 risk class. This control is the same as that prescribed by AMDD, and is aligned to the AMDD.

<p>ARTICLE 5</p>	<p>In Article 5:- (1) A medical device shall be assessed by the regulatory authority of a Member State, or any appointed bodies recognized by a Member State, as the case may be, and should be in conformity and in compliance with the requirements laid down in this Medical Device Directive and other relevant laws and regulations of a Member State.</p>	<p>Section 11 of the Act, conformity assessment of medical devices in Malaysia is performed by 3rd party independent body. Malaysia system of carrying out conformity assessment by 3rd party CAB is compliant to AMDD.</p>
<p>ARTICLE 6</p>	<p>Registration and Placement on the Market</p>	<p>AMDD requires that any medical device placed in the market of an ASEAN member state (“AMS”) must be registered. Malaysia system of registration of a medical device, per section 5 of Act 737 that imposes requirement for registration of medical device, is compliant to the AMDD.</p>
<p>ARTICLE 7</p>	<p>Registration of Persons responsible for placing medical devices on the markets of member states</p>	<p>AMDD requires that any person placing in the market of an AMS any medical device must be registered. Malaysia system of imposing requirements for establishment licensing, per section 15 of the Act, is compliant to the AMDD.</p>

<p>ARTICLE 8</p>	<p>Technical Documents for Medical Devices</p> <ul style="list-style-type: none"> -ASEAN CSDT -Post Marketing Alert System (PMAS) Requirements -Declaration of Conformity (DOC) 	<p>Vide the Schedules of Reg2012, Malaysia has required that all establishments placing medical devices in the market comply with these technical documents.</p>
<p>ARTICLE 9</p>	<p>Reference to Technical Standards</p>	<p>Adopted by MDA</p>
<p>ARTICLE 10</p>	<p>Labeling</p> <p>In addition, pursuant to Article 10-(3) of the AMDD, Member States may set the requirement for having the label of a medical device in their national languages.</p>	<p>The labeling requirements imposed in Malaysia, Sixth Schedule of Reg 2012, are aligned to AMDD.</p> <p>Malaysia has exercised this clause of the AMDD, by imposing vide Part II, item 5-(1) of the Sixth Schedule of Reg 2012, that the use of Bahasa Malaysia shall be required for home-used medical devices. Further, item 5-2 states that the Authority may, as it thinks fit, require the use of Bahasa Malaysia for other types of medical devices.</p>

<p>ARTICLE 11</p>	<p>Medical Device Claims</p>	<p>Pursuant to section 44-(2) of Act 737, no person shall make any misleading or fraudulent claims in respect of a medical device in any advertisement. Penalties of fines and/or jail terms are imposed for contraventions. In addition, the Trade Description Act is also actively enforced in Malaysia.</p>
<p>ARTICLE 12</p>	<p>Post-marketing Alert System</p>	<p>Pursuant to sections 38 to 42 of Act 737, Malaysia has written into law and imposed onto licenses and permit holders a series of post market duties and obligations.</p>
<p>ARTICLE 13</p>	<p>Clinical Investigation</p> <p>Article 13-(2) states that Regulatory Authority may require that the clinical investigations be conducted in accordance with the provisions of Annex 8 (Clinical Investigation).</p>	<p>Gap Identified: To explore the need to regulate all aspects of clinical investigation, including but not limited to every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results.</p>

SCHEDULE	CONTENTS	ANNEX	CONTENTS
SCHEDULE 1	Rules of Classification of Medical Devices	ANNEX 2	Risk Classification Rules for Medical Devices other than IVD Medical Devices
		ANNEX 3	Risk Classification Rules for IVD Medical Devices
SCHEDULE 2	Rules of grouping of medical devices		
SCHEDULE 3	Conformity assessment procedures Appendix 1: Essential principles of safety and performance of medical devices Appendix 2: Common Submission Dossier Template Appendix 3: Declaration of Conformity (DOC)	ANNEX 1	ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES
		ANNEX 4	ASEAN Common Submission Dossier Template
		ANNEX 6	Components Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC)
SCHEDULE 4	Requirements for registration of CAB		
SCHEDULE 5	Table of fees		
SCHEDULE 6	Requirements for Labelling		
		ANNEX 5	Post Marketing Alert System (PMAS) Requirements



↓ Transpose AMDD into National Laws

National Laws of Member States for Medical Device Control

MALAYSIA has transpose almost all AMDD articles in Act 737

1ST AMDC MEETING



THE 1ST ASEAN MEDICAL DEVICE COMMITTEE (AMDC) MEETING AND RELATED EVENTS

30th NOV - 3rd DEC 2015
KUALA LUMPUR, MALAYSIA



AMDC

- AMDC to develop milestones for the completion of transposition process and submission of instrument of ratification by 2020.
- In addition, AMDC to discuss on the following, but not limited to:
 - I. Development of Guidelines for implementation of AMDD;
 - II. Implementation of AMDD in phases;
 - III. Grace period for industries;
 - IV. Monitoring of the implementation of AMDD.

THANK YOU



**Pihak Berkuasa Peranti Perubatan
KEMENTERIAN KESIHATAN MALAYSIA**